UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/422,613	10/17/89	KUBERASAMPATH T	CRP042

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EXAMINER	
NUTTER, N	
ART UNIT	PAPER NUMBER
153	5

DATE MAILED: 04/06/90

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 26 Feb 1990 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~days~~ from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 34 are pending in the application.
   Of the above, claims 1 - 19 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 20 - 34 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Applicant's election of Group II, claims 20-34 in Paper No. 4 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

The submission of the Abstract with Paper No. 4 is acknowledged and appreciated.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 20-34 are rejected under 35 U.S.C. 103 as being unpatentable over Wang et al (WO 88/00205), Jefferies ('370) Sampath et al (PNAS Vol 80) in view of Thiele et al.

The reference to Wang et al teaches the conventionality of producing a matrix suitable for implantation which comprises providing demineralized bone

particles, extracting protein with guanidine and subsequently a urea containing buffer, washing the particles and finally adsorbing osteogenic protein onto the particles. Note Example 1, page 12 (lines 15-17) for the demineralization of ground bone. At (lines 21-25) the patent teaches the employ of guanidine and at page 13 (lines 7-9) the use of urea as in instant claim 21. Note the washing steps at page 12 (lines 21-25) and the employ of osteogenic protein at page 16 (lines 6-8) as in instant claims 30 and 33.

The PNAS article to Sampath et al teaches the use of bone particles of 74-420 μm, which lies within the range recited in the instant claims. The employ of guanidine-HCl is suggested in the Abstract. Note page 6591, last full paragraph, for reconstitution and subsequent lyophilization.

The patent to Jefferies teaches a process employing demineralized bone particles which are extracted with a strong acid, washed 6 times (note Example I) and subsequnetly complexed with an osteogenic factor (note Part B of Example I).

The reference to Thiele et al teaches a process for producing bone matrix materials which starts with demineralized bone particles which are treated with a swelling agent with subsequent addition of an inert mucopolysaccharide thereto.

Although Sampath et al, Jefferies and Thiele et al employ agents othen than guanidine as recited in dependent claim 21 they produce the demineralized bone particles as recited in broad claim 21. Sampath et al suggest the use of guanidine. Wang et al are specific to its use. Further, although Thiele et al employ an inert mucopolysaccharide, the reference is relied upon solely to show the swelling step for enhanced adsorption of other agents. The choice of particular agents either for the demineralization or for the swelling step is not deemed to be critical, and nothing on the record has established this to be so. Since all steps in the production of these matrices are shown by the prior art which are all analogous, subsequent use of them to produced the matrix of the instant claims would have been obvious to a practitioner having an ordinary skill in the art at the time the invention was made, in the absence of any showing of unexpected results.

Nathan M Nutter

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4/4/90

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PATENT EXAMINER
ART UNIT 153